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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/030,985	02/26/98	FALO JR	L 214001-00648

HM12/0808

DIANE R MEYERS
ECKERT SEAMANS CHERIN & MELLOTT
600 GRANT STREET
42ND FLOOR
PITTSBURGH PA 15219

EXAMINER

VANDER VEGT, F

ART UNIT

PAPER NUMBER

1644

27

DATE MAILED:

08/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

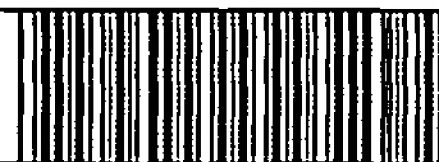
Office Action Summary

Application No.
09/030,985

Applicant(s)
Falo et al

Examiner
F. Pierre VanderVegt

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15 and 17-24 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15 and 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

DETAILED ACTION

This application claims priority to provisional application 60/039,472.

Claims 13-15 and 17-24 are currently pending in this application.

- 5 1. Applicant is advised that the Utility Examination Guidelines (Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001) were published subsequent to the prior Office Action and the claims have been examined in view of these guidelines. The following rejections are set forth herein.

10 Due to the fact that prosecution is being reopened, the potential Examiner's Amendment discussed with Applicant's representative Diane Myers on February 13, 2001 has not been entered. This Office Action is made **NON-FINAL**.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

15 Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- 20 3. Claims 13-15 and 17-24 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible asserted utility or a well-established utility.

25 Claims 13-15 and 17-24 are drawn to a composition comprising the products of co-culture of antigen presenting cells and tumor cells. The claimed compositions are not supported by either a specific and substantial asserted utility or a well-established utility. The sole utility asserted for the claimed compositions is for the introduction into a subject, including a human, of the composition for the treatment of cancer. The claims read directly upon the reintroduction of living cancer cells into a subject, as the products of co-culture are not necessarily APC-tumor fusions and the composition is not necessarily killed. No credible utility for administering to a human active tumor cells is indicated. In all examples provided in the instant specification, all of which use well-characterized murine tumor models, the cells administered to the subject animals are first

irradiated. Further, the murine tumor cell lines used in the examples, B16 and 3LL are well known in the art to be highly immunogenic. Contrary to these exemplified murine tumors, human tumors are poorly immunogenic (Fenton et al, U3 on form PTO-892). The instant examples, even those where administration of the claimed composition results in reversal of 'established' tumors, are carried out within a fairly short time-frame, i.e., the animal is administered a large tumor burden initially to establish the tumor followed rapidly by the administration of presenting cells, such as the hybrids, which are extensively loaded with tumor antigen(s), priming T cells to react with cell antigens of a tumor which has not needed to mutate in order to evade the immune system and survive. Contrarily, spontaneous tumors which arise in a subject from an initially low tumor cell burden overcome immune attack by mutation to escape immune recognition by mechanisms such as heterogeneity of MHC Class I expression and allele-specific loss of important tumor antigens (Fenton et al, page 242, second column in particular). While Applicant may have demonstrated that highly immunogenic tumors may be treated using the claimed composition when the tumor cells remaining in the composition have been killed, there is no credible evidence provided that less immunogenic tumors of humans can be similarly treated, or that the composition can be used against tumors which arose spontaneously and successfully evaded the immune system to allow them to become established from an initially low tumor burden. See *Brenner v. Manson*, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

4. Claims 13-15 and 17-24 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by a credible asserted utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

5. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2001 365-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
August 7, 2001



**F. PIERRE VANDERVEGT
PATENT EXAMINER**